

REMARKS

The applicants have studied the Office Action dated June 9, 2006, and have amended the claims. By virtue of this amendment, claims 16 and 32-34 are now pending, claims 16 and 32 have been amended and claims 33 and 34 have been added. It is submitted that the application is in condition for allowance by virtue of this amendment. Reconsideration and allowance of all of the claims in view of the following amendment and remarks is respectfully requested.

Claims 16 and 32 were rejected under 35 U.S.C. § 103 as being unpatentable over Kurnik (U.S. Patent 6,272,364) as modified by Hiroi et al. (US Patent 5,745,362). This rejection is respectfully traversed.

The embodiments of the present invention are directed to infusing a liquid based on the commands from a PID controller using a current blood glucose concentration of the user. Independent claim 16, as amended, recites "obtaining a current blood glucose concentration of the user; generating a controller input based on the current blood glucose concentration, generating commands by a proportional plus, integral plus, derivative (PID) controller from the controller input using at least one preset controller gain, wherein the PID controller is a bilinear PID controller; and infusing the fluid based on the commands from the PID controller" (emphasis added). Claim 32 recites similar language. Support for the amendment exists throughout the specification. For example, "glucose sensors may be inserted through the IV line to give real-time glucose levels from the blood stream" (p.14, line 1-2). No new matter has been added.

The Kurnik and the Hiroi et al. references neither describe nor suggest the invention of claims 16 or 32, either alone or in combination. Specifically, the Kurnik reference does not use current blood glucose concentration to generate commands for the infusion process. Instead, Kurnik reference only teaches using predicted values in controlling a pump for insulin delivery. For example, the Kurnik reference states on col. 23, lines 42-44: "use of the TSES function of

Equation (7) allows for accurate predictions of either real-time or future blood glucose values" (emphasis added). This is because the Kurnik reference teaches the use of iontophoresis to measure glucose values, which has about a 15 minute lag time. Thus, predictive glucose value is key aspect of their invention since current glucose values cannot be used. See Example 1, col. 24 which explains the "15 minute measurement cycles." Thus, Kurnik reference does not describe or teach the use of current blood glucose concentration as recited in the claims, and Hiroi et al. does not make up for the deficiencies of the Kurnik reference. The Hiroi reference was merely cited for the teaching that a PID controller was known in the art, albeit in non-analogous art.

However, more importantly, in the Office Action, the Examiner stated that "it would have been obvious ... to modify Kurnik with a bilinear PID controller as taught by Hiroi et al, since such a modification would provide the method a more accurate control system." The applicants respectfully disagree that it would be obvious to modify the Kurnik reference with a bilinear PID controller. Although the prior art has long talked about trying to obtain "an artificial pancreas" (i.e. a device that can both sense glucose levels and deliver insulin accordingly), the ability to actually provide a control system that would mimic the pancreas has seen a long list of failures over twenty years. Substituting the control aspects of the Kurnik reference would be substituting the heart of the Kurnik invention. Not only does the fact that different types of sensor chemistry and sensor structure would limit what control system can be used, one of ordinary skill in the art would not be able to substitute a PID controller with the invention of the Kurnik reference. The Kurnik reference attempts to only use past glucose values to predict future glucose values. There is no description on what PID controller would be attempting to mimic. Without any teaching on Beta cell responses and how one tries to replicate the function of a Beta cell, there would be no way one that one of ordinary skill in the art can just use a PID controller with the Kurnik reference. It is respectfully submitted that the Examiner is engaging in improper hindsight reconstruction of the claimed invention.

The Federal Circuit has consistently held that hindsight reconstruction does not constitute a prima facie case of obviousness under 35 U.S.C. § 103. *In re Geiger*, 2 USPQ2d 1276 (Fed Cir. 1987). Thus, rather than pointing to what the prior art discloses and teaches as to making the

suggested combination, the final Office Action relies on assumptions and statements without any support in the record. All these statements represent shortcuts to a conclusion of obviousness devoid of the required analytical approach based on what is actually in the prior art. Thus, it is clear that the Examiner is relying on impermissible hindsight to avoid express limitations in the claims and come up with unsupported and hypothetical teachings to thereby recreate the applicants' claimed invention. Therefore, the Examiner has failed to establish a prima facie case of obviousness.

In addition, given that the Hiroe et al. reference does not provide any motivation to apply a PID controller to the medical arts and more specifically to mimic the Beta cell of a pancreas, it is respectfully submitted that it was improper to combine the two references. It is well-settled that a reference must provide some motivation or reason for one skilled in the art (working without the benefit of the applicants' specification) to make the necessary changes in the disclosed device. The mere fact that a reference may be modified in the direction of the claimed invention does not make the modification obvious unless the reference expressly or impliedly teaches or suggests the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984); *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. App. 1985); *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. App. 1984).

The Kurnik and Hiroe et al. references fail to meet the basic requirement for a finding of obviousness established by the courts in *Gordon*, *Clapp*, and *Chicago Rawhide*. There is no suggestion in the cited references of modifying the devices disclosed therein in the direction of the present invention, nor is there any suggestion whatsoever of the desirability of such modification. Thus, it is respectfully submitted that the ordinarily skilled artisan would have had no motivation to provide the inventions recited in claims 16 and 32.

Therefore, for all of the above reasons, it is respectfully submitted that the rejection of claims 16 and 32 under 35 U.S.C. § 103 should be withdrawn.

New claims 33 and 34 further claim additional limitations on how the PID controller replicates the insulin response of the Beta cell. Support for the claims can be found on page 16 of the specification. No new matter was added.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Northridge, California, telephone number (818) 576-4110, to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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